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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/809,635 | 03/24/2004 | Jun Feng | DPP-IV-5004-U | 8938 |

32793 7590 09/12/2007
TAKEDA SAN DIEGO, INC.
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SAN DIEGO, CA 92121

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| EXAMINER |
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HABTE, KAHSAI

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| ART UNIT | PAPER NUMBER |
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1624

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| MAIL DATE | DELIVERY MODE |
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09/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/809,635

Applicant(s)

FENG ET AL.

Examiner

Kahsay Habte

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-17, 19, 22-25, 27, 38, 52-54, 56 and 111-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-17, 19, 22-25, 27, 38, 52-54, 56 and 111-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>7/5/07 & 4/5/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 8-17, 19, 22-25, 27, 38, 52-54, 56 and 111-114 are pending in this application.

Response to Amendment

2. Applicant's amendment filed 8/7/2007 in response to the previous Office Action (8/9/2006) is acknowledged. Rejection of claims 8-17, 19-20, 22-25, 27, 38, 52-54, 56 and 111 under 35 U.S.C. § 112, second paragraph (item 14a) and the prior art rejection (items 5-11) have been obviated. The obviousness-type double patenting rejection (item 13) and the second paragraph rejection (item 14b) have been maintained. Even though applicants overcome the rejections raised in previous Office Action, applicant's amendment raises new issue that needs further rejection.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 8-17, 19, 22-25, 27, 38, 52-54, 56 and 111-114 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5, 19-21, 23, 26-31, 33, 36, 42-43 and 55-61 of copending Application No. 10/809,636. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims 8-17, 19, 22-25, 27, 38, 52-54, 56 and 111-114 and claims 1, 3-5, 19-21, 23, 26-31, 33, 36, 42-43 and 55-61 of copending Application No. 10/809,636.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments

Applicant's argument filed 8/07/2007 has been fully considered but it is not persuasive.

Applicants intend to address the rejection when one or both of the applications are otherwise in condition for allowance.

5. Claims 8-17, 19, 22-25, 27, 38, 52-54, 56 and 111-114 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13, 27-29 and 31 of copending Application No. 10/809,637. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims 8-17, 19, 22-25, 27, 38, 52-54, 56 and 111-114 and claims 13, 27-29 and 31 of copending Application No. 10/809,637.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-17, 19, 22-25, 27, 38, 52-54, 56 and 112-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 38 (page 7) in the definition of R_{12} , the phrase "each R_{12} carbonyl group," is not clear. Carbonyl is a divalent substituent. How is carbonyl substituent substituted on the alkyl group? Do applicants mean an oxo group substituted on alkyl? Note that carbonyl ($C=O$) is different from an oxo group ($=O$). If a carbonyl is substituted on alkyl, the molecule becomes charged. It is recommended that applicants delete the phrase "carbonyl group" or replace it with "oxo".

Response to arguments

Applicant's argument filed 8/07/2007 has been fully considered but it is not persuasive.

Applicants did not address the "carbonyl" issue, instead deleted "oxo" from the definition of R_{12} or other variables.

b. In claim 38 or elsewhere in the claims, the phrase "alicyclic, aliphatic" is not what is covered and what is not? Aliphatic what? It is recommended that applicants delete said phrase e.g. from claim 38 or other claims where it appears.

Information Disclosure Statement

7. Applicant's Information Disclosure Statement, filed on 7/5/2007 and 4/5/2007 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

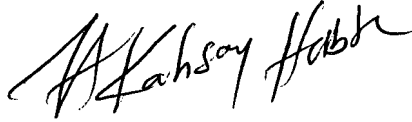
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Kahsay Habte", written in a cursive style.

Kahsay Habte
Primary Examiner
Art Unit 1624

September 10, 2007